REMARKS

Claim Amendments

Independent claims 1, 7, 8, 15, 23, and 38 have been amended to remove the step labels. Such amendments do not change the scope of the claims.

Claims 5, 7, 15 have also been amended regarding the sagittal plane. Support for these amendments can be found throughout the specification and drawings, *see, e.g.*, Figs. 72-73 and accompanying text.

Claims 20, 21 have been amended to correct clerical errors, without narrowing the scope thereof.

Claim 23 has also been amended regarding the sagittal plane and the distraction guide. Support for these amendments can be found throughout the specification and drawings, *see, e.g.*, Figs. 79-98 and accompanying text.

Claims 28, 33 have been amended to now depend from claim 23.

Claims 29-32, 34-36 have been canceled.

Claims 51-52 have been added. Support for these amendments can be found throughout the specification and drawings, *see, e.g.*, Figs. 65-66 and accompanying text.

None of these amendments introduce new matter.

Claim Rejections

Claims 1-47 stand rejected under §102(e) as being anticipated by U.S. Patent No. 5,562,662 (Brumfield). Claims 1 and 48-50 stand rejected under §102(e) as being anticipated by U.S. Patent No. 5,645,599 (Samani). Applicant requests reconsideration.

Rejections over Brumfield

Independent claim 1 requires, *inter alia*, "inserting the interspinous process implant between the upper and the lower spinous processes from a first lateral side of the spinous processes." The Action asserts that Brumfield teaches this aspect at Fig. 2 and col. 9, lines 55-57. Assuming *arguendo* that the Brumfield transverse connector 38 extends through the "bores in ref. 29" as asserted in the Action, such does not mean

that these transverse connectors are necessarily inserted between the upper and the lower spinous processes from a first lateral side as claimed. Nowhere does the text of Brumfield describe a lateral insertion; the cited text merely mentions the transverse connectors 38 extend through the rod connectors, but does not mention when this occurs. Applicant submits that the transverse connectors 38 may be added to the Brumfield spinal construct prior to inserting the same into the patients body, and the transverse connectors could easily be placed as shown in Fig. 2 by simply inserting the spinal construct in a posterior-to-anterior direction. Such would seem completely consistent with Brumfield, and nothing in Brumfield has been identified that indicates this is incorrect. As such, Brumfield neither explicitly nor inherently teaches "inserting the interspinous process implant between the upper and the lower spinous processes from a first lateral side." Accordingly, Brumfield cannot anticipate the subject matter of independent claim 1, or its dependent claims.

Independent claims 7, 8, 15, 23, and 38 likewise require lateral insertion of a portion of the implant. For example, claim 7 requires "inserting the interspinous process implant between the spinous processes from a first lateral side" while claim 15 requires "inserting the interspinous process implant laterally between the spinous processes." Applicant submits that these independent claims, and their respective dependent claims, define patentable subject matter over Brumfield for reasons similar to those discussed above with respect to independent claim 1.

With further regard to dependent claim 5, this claim requires "causing a retaining portion of the implant that passed laterally through a sagittal plane defined by the upper and lower spinous processes to extend superiorly or inferiorly generally along a lateral side of at least one of the upper and lower spinous processes." On this point, Applicant notes that the Brumfield transverse connector 38 -- the only item in Brumfield that appears to extend through (or is alleged to pass through) a sagittal plane defined by spinous processes -- extends only laterally, and no portion thereof appears to extend along a lateral side of the spinous processes. As such, Applicant submits that dependent claim 5 is patentable over Brumfield for this additional reason.

With further regard to independent claim 7, this claim requires "causing the interspinous process implant ... to deploy so that a member of the interspinous process implant that was urged through the sagittal plane projects outwardly and superiorly or inferiorly from a body of the interspinous process implant adjacent a second lateral side of at least one of the spinous processes." Applicant submits that Brumfield does not show this arrangement for reasons similar to those expressed above with respect to claim 5. Accordingly, Applicant submits that independent claim 7 defines patentable subject matter over Brumfield for this additional reason.

With further regard to independent claim 15, this claim requires "passing the implant member laterally through a sagittal plane defined by the spinous processes," and "wherein the deploying comprises changing a relative orientation between the implant member and the body." On this point, Applicant notes that the Brumfield transverse connector 38 -- the only item in Brumfield that appears to extend through (or is alleged to pass through) a sagittal plane defined by spinous processes -- is not alleged to have portions that change their relative orientations to each other. As such, Applicant submits that independent claim 15, and its dependent claims, are patentable over Brumfield for this additional reason.

With further regard to independent claim 23, this claim requires that the distraction guide "expand[] in a direction toward the proximal end of the body," and also requires "passing the distraction guide laterally through a sagittal plane defined by the spinous processes." The Action identifies the fixation hook 25 in Brumfield as the putative distraction guide. Applicant submits that one of skill in the art would not consider the Brumfield fixation hook 25 as being the claimed distraction guide. Further, the Brumfield fixation hook 25 does not appear to expand in a direction toward the proximal end of the "body" (which is alleged to be the transverse connector 38). Further still, the Brumfield fixation hook 25 is nowhere described as being passed through the sagittal plane of the spinous processes during its insertion. As such, Applicant submits that independent claim 23, and its dependent claims, are patentable over Brumfield for this additional reason.

With further regard to independent claim 38, this claim requires that the implant include "a body adapted to be placed between spinous processes, the body having a proximal end defining a first saddle, and a distal end defining a second saddle," wherein "the first saddle and the second saddle are adapted to receive adjacent spinous processes". The Action identifies two rod connectors 28 in Brumfield Fig. 2 as the claimed saddles. The individual rod connectors 28 in Fig. 2 do not appear to have two "saddles" of any kind, much less two saddles that are adapted to receive adjacent spinous processes as claimed. Applicant further notes that Figs. 3A-3C of Brumfield show the rod connector 28 in greater detail, and that there are no two such saddles apparent in Figs. 3A-3C. As such, Applicant submits that independent claim 38, and its dependent claims, are patentable over Brumfield for this additional reason.

With further regard to new dependent claims 51-52, these claims require "passing at least a portion of the first saddle through a sagittal plane defined by the spinous processes" as part of the inserting step. There is no discussion or illustration identified in Brumfield that shows or suggests passing the rod connectors through the sagittal plane. As such, Applicant submits that dependent claims 51-52 are patentable over Brumfield for this additional reason.

Rejections over Samani

Independent claim 1 requires, *inter alia*, "inserting the interspinous process implant between the upper and the lower spinous processes from a first lateral side of the spinous processes." The Action asserts that Samani teaches this aspect at Fig. 3. However, there is no explicit or inherent teaching in Samani that the implant 1 is inserted laterally. No text has been cited in the rejection that explicitly states that the implant is inserted laterally. Nor does anything in Fig. 3 suggest otherwise. To the contrary, the shear length of the "brackets" 6 shown in Fig. 3 suggests that they cannot be inserted between the spinous processes 2 from a lateral direction (e.g., in the plane of the paper for Fig. 3). See also, Fig. 2. Instead, it appears that the Samani device is inserted into position in a posterior-to-anterior direction. Thus, Samani neither explicitly nor inherently teaches "inserting the interspinous process implant between the upper

and the lower spinous processes from a first lateral side of the spinous processes." Accordingly, Samani cannot anticipate the subject matter of independent claim 1, or its dependent claims.

Request for clarification of the record

As indicated above, one issue in this case is whether Brumfield or Samani teach lateral insertion of the implant between the spinous processes. Applicant submits that one of skill in the art would understand that "inserting from a lateral side," "inserting the [] implant laterally between [the spinous processes]," "laterally inserting", and similar language means inserting in a direction generally into or out of the plane of the paper in Fig. 2 of Samani. Such direction would also be generally parallel to the plane of the paper in Samani Fig. 3. These figures are reproduced below for reference.

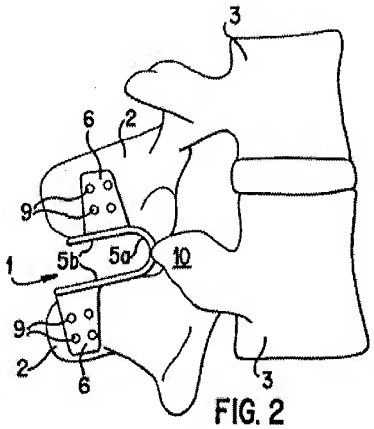

FIG. 2

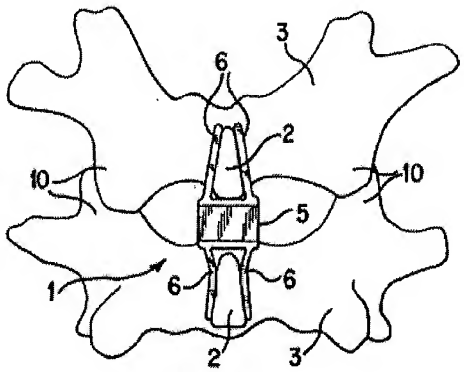

FIG.3

If the Examiner is applying some other interpretation to the term "lateral," the Examiner is requested pursuant to MPEP §706.07 to clarify the interpretation being applied via an annotated illustration based on Figs. 2-3 of Samani in the next communication.

In view of the above amendments and remarks, the Applicant submits that the present application is in condition for allowance and such action is respectfully requested.

Respectfully submitted,
COATS & BENNETT, P.L.L.C.

Dated: September 23, 2008

John R. Owen
Registration No.: 42,055
Telephone: (919) 854-1844
Facsimile: (919) 854-2084